

**Remarks**

In view of the above amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested.

This submission is accompanied by a Request for Continued Examination, a petition for extension of time, and an information disclosure statement. Because the Notice of Appeal was entered on September 4, 2007, this submission is timely. All fees should be withdrawn from Deposit Account 14-1138.

Claim 1 has been amended to recite higher stringency requirements (i.e., structural requirements of the claimed subunit based on hybridization capability of the encoding nucleic acid) as well as functional requirements of the encoded delta subunit (“cooperate with delta prime and tau/gamma subunits to form a clamp loader complex”). The latter limitation finds descriptive support in the background of the invention at page 2, line 18 to page 3, line 31.

Claim 1, 2, 7-9, 15, and 16 have been amended, and claims 4, 5, and 14 have been cancelled without prejudice. Claims 1, 2, 7-13, and 15-21 are pending, with claims 17-21 being allowed.

The objection to claims 4 and 5 for reciting non-elected subject matter is overcome by the cancellation of this claim. Non-elected subject matter has also been withdrawn from claim 1. Therefore, the objection should be withdrawn.

The rejection of claims 1, 2, and 4-16 under 35 U.S.C. §112 (first paragraph), as lacking written descriptive support, is respectfully traversed.

The U.S. Patent and Trademark Office (“PTO”) maintains its position that the single species disclosed as SEQ ID NO: 178 (*Bacillus stearothermophilus* delta subunit) does not provide descriptive support for the genus as claimed. Applicants respectfully disagree.

Given the recitation of high stringency conditions in claim 1 (hybridization and wash conditions of 5X sodium citrate buffer and at a temperature of 65°C), persons of skill in the art would expect hybridizing nucleic acids to be structurally similar to the nucleic acid sequence of SEQ ID NO: 177, and that the encoded delta subunit would be structurally and functionally similar to the delta subunit of SEQ ID NO: 178. *See EnzoBiochem Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1327, 63 USPQ2d 1609, 1615 (citing U.S. Patent and Trademark Office “Synopsis of Application of Written Description Guidelines” with

approval). Given this rational expectation, persons of skill in the art would also expect related organisms (i.e., from bacterial genus *Bacillus* or, now, *Geobacillus*) to share functional and structural similarities, including similarities in the structure and function of individual genes.

The reasonableness of that expectation is confirmed by applicants' August 24, 2006, submission (Exhibits 1-3 attached thereto), which demonstrated relatedness between the *B. stearothermophilus hola* and delta subunit of SEQ ID NOS: 177 and 178, and the *Geobacillus kaustophilus hola* and delta subunit. As one of ordinary skill in the art would have expected, species of delta subunits from thermophilic organisms that belong to the biological classification *Bacillus* or *Geobacillus* clearly share similar structure and, therefore, function.

Given the above facts, applicants respectfully submit that the present application provides written descriptive support for the claimed subject matter. Therefore, the rejection of claims 1, 2, 4-16 for lack of written description should be withdrawn.

The rejection of claims 1, 2, and 4-16 under 35 U.S.C. §112 (first paragraph) for lack of enablement is respectfully traversed.

It is the position of the PTO that the specification does not provide sufficient guidance for making and using other delta subunits within the scope of the claims. Applicants respectfully disagree.

Because the application adequately describes the presently claimed genus, persons of skill in the art would be fully able to obtain other polynucleotides encoding other delta subunits within the claimed genus, and then make and use those delta subunits in the manner described in the specification.

The present application provides the nucleotide sequence of *Bacillus* (now *Geobacillus*) *stearothermophilus hola* (e.g., SEQ ID NO: 177) and describes how one of ordinary skill can isolate homologs of the disclosed sequence (*see* page 41, line 9 to page 42, line 29), express the delta subunit of SEQ ID NO: 178 or delta subunits encoded by such homologous *hola* sequences (*see* Example 19, expressing *A. aeolicus* delta subunit), and test the encoded delta subunit for clamp loader assembly competence (*see* Examples 24 and 25, testing *A. aeolicus* clamp loader assembly) and for clamp loader activity (*see* Examples 26 and 30, testing *A. aeolicus* clamp loader activity). Thus, one of ordinary skill in the art would have been fully able to make and use the claims delta subunits within the scope of the presently claimed invention.

As noted in applicants' prior submission, method 3 for homolog identification, described at page 42, is precisely the approach used to identify the *holA* homolog shown in Exhibit 1 of applicants' prior submission. For this reason, it should be apparent that the present application fully enables the production and use of other homologous species of *Bacillus* or *Bacillus* (now *Geobacillus*) *stearothermophilus* delta subunits.

In view of all of the foregoing, applicants submit that the rejection of claims 1, 2, and 4-16 for lack of enablement is improper and should be withdrawn.

In view of all of the foregoing, applicant submits that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

Date: March 3, 2008

/Edwin V. Merkel/  
Edwin V. Merkel  
Registration No. 40,087

NIXON PEABODY LLP  
1100 Clinton Square  
Rochester, New York 14604  
Telephone: (585) 263-1128  
Facsimile: (585) 263-1600